

REMARKS

These remarks are in response to the office action mailed May 2, 2008. Claims 41 and 42 have been amended. Support for the amendments can be found, for example, at paragraph [0073]. No new matter is believed to have been introduced.

I. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 41 and 42 stand rejected as allegedly unclear regarding what dose/fluence is claimed. Applicants respectfully submit that claims 41 and 42 specifically recite in the alternative four (4) different dose/fluences. Applicants submit that the claim is clear and definite and respectfully request withdrawal of the rejection.

II. REJECTION UNDER 35 U.S.C. §103

Claims 1-8, 10-12, 14, 16-17, 24 and 41-42 are rejected under 35 U.S.C. §103 as allegedly unpatentable over Levy et al. (U.S. Patent No. 5,798,349) in view of Jampol et al. Applicants respectfully traverse this rejection.

The Applicants recognized that one can treat neovascularization of the eye by treating extrafoveal feeder vessels with doses of energy in excess of what one would use to treat the foveal or subfoveal areas of the eye. Furthermore, Applicants recognized the importance of treating and the advantages of treating feeder vessels in the extrafoveal areas.

The Applicants respectfully submit that even under the relaxed standards of *KSR v. Telflex*, the Office must still demonstrate each and every element of Applicants' claimed invention to provide a *prima facie* case of obviousness. Furthermore, when viewing the more unpredictable arts (e.g., biotechnology, medical therapies) the "teaching, suggestion and motivation (TSM)" test is appropriate. Unlike the predicable art having easily combined elements, the unpredictable arts lack the ease of combining elements with a predictable result. As described below the Office has failed to provide each and every element either in the references cited in the Final Office Action or in the knowledge available to one of skill in the art. Applicants will make the clear in the remarks below.

Applicants submit that because no claims have been amended there is no further search required and accordingly the references current under consideration are fully addressed. Furthermore, it would be improper for the Examiner to maintain the Final Office Action and thus requiring an Appeal or a Request for Continued Examination in view of additional positions or recombined reference by the Office not currently elaborated in Final Office Action; the Office must provide the Applicants sufficient opportunity to address any further rejections.

Levy *et al.* do not teach or suggest (i) topical application of a photosensitizer, (ii) use of a high speed scanning laser ophthalmoscope, (iii) the use of indocyanine green, (iv) the use of non-coherent light, and/or targeting (e.g., identifying and exposing) choroidal neovascularization in the extrafoveal area, or (v) identifying a feeder vessel in an extrafoveal area. As the invention describes identifying and treating a feeder lay is important in stopping neovascularization in the extrafoveal area. Typically PTD treats neovascularization as a whole in a region of vessel growth. Furthermore, typical PTD known at the time of conception of the present invention was directed to the foveal area using doses below 50 J/cm² to prevent damage. Finally, typical PTD known at the time of conception of the present invention did not target feeder vessels in the extrafoveal area.

To overcome these deficiencies the Office combines Jampol *et al.* with Levy for the alleged teaching of exposing the extrafoveal area to PDT. Jampol *et al.*, however, do not discuss or described identifying a feeder vessel in the extrafoveal area. As described in the present application the importance identifying a feeder layer is important in reducing further neovascularizaiton. "The advantage to treating feeder vessels is the possibility that a large CNV complex can be eliminated by closing a small number of feeder vessels. Further, feeder vessels are generally localized to an area outside the central portion of the macula (i.e., the vessels are "extra-foveal")." (paragraph [0009] of publication no. 20060258629). Levy *et al.* in combination Jampol *et al.* fail to teach, suggest or contemplate these aspects. Thus, the combination of references does not teach and suggest all of the elements of Applicants' claimed invention. Accordingly, the reference cannot render the claimed invention obvious.

Claims 1-8, 10-12, 14, 16-17, 24, and 41-42 stand rejected under 35 U.S.C. §103 as allegedly unpatentably over Sullivan in view of Jampol et al. and further in view of Miller et al. Applicants respectfully traverse this rejection.

Sullivan does not teach or suggest (i) topical application of a photosensitizer, (ii) use of a high speed scanning laser ophthalmoscope, (iii) the use of indocyanine green, (iv) the use of non-coherent light, and/or (v) photodynamic therapy of a feeder vessel in an extrafoveal region or area. In addition, Sullivan does not teach or suggest photodynamic therapy using a dose that is about 4x the standard recognized dose of about 12 J/cm² (e.g., about 50 J/cm²). As the Examiner admits, Sullivan et al. do not teach the method for treating an aberrant choroidal neovascularization in an extrafoveal area of the eye or the fluence of the photoactivating light.

Furthermore, if the Examiner takes the teachings of the reference being cited as a whole, Sullivan et al. teach away from such higher doses indicating that "the benefits of laser treatment are limited because laser photocoagulation damages the viable neurosensory retina. . ." (see, e.g., page 398 of Sullivan et al.). Such neurosensory portions of the retina include the foveal area.

Thus, Sullivan does not teach each and every element of Applicant's claimed invention and in fact teaches away from the invention.

To overcome the deficiencies of Sullivan et al., the Office combines Jampol et al. However, as described above, Jampol et al. also fails to teach or suggest at least the same elements as Sullivan et al.

Jampol et al. do not discuss or described identifying a feeder vessel in the extrafoveal area. As described in the present application the importance identifying a feeder layer is important in reducing further neovascularization. "The advantage to treating feeder vessels is the possibility that a large CNV complex can be eliminated by closing a small number of feeder vessels. Further, feeder vessels are generally localized to an area outside the central portion of the macula (i.e., the vessels are "extra-foveal")." (paragraph [0009] of publication no. 20060258629). Levy et al. in combination Jampol et al. fail to teach, suggest or contemplate these aspects. Thus, the combination of references does not teach and suggest all of the elements

of Applicants' claimed invention. Accordingly, the reference cannot render the claimed invention obvious.

To further overcome the deficiencies of Sullivan and Jampol et al., the Office further adds Miller et al. Miller et al. allegedly porphyrin administration for neovascularization. Miller et al. do not teach foveal or extrafoveal treatment or feeder vessel treatment in the extrafoveal area. Accordingly, the combination of Sullivan, Jampol et al., and Miller et al. if combined, which there is no suggestion for such a combination, fail to teach or suggest all the elements of Applicants' claimed invention. Accordingly, the rejection should be withdrawn.

Claims 1-12, 14, 16-17, 24, and 41-42 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over Levy et al, in view of Jampol et al. and further in view of Levy et al. (U.S. Patent No. 4,920,143). Applicants respectfully traverse this rejection.

The rejection of claim 1-8, 10-12, 14, 16-17, 24 and 41-42 over Levy in view of Jampol et al. was addressed above. Levy et al. ('143) is combined for the alleged teaching of topical application of a photosensitizer. Applicants respectfully submit that the addition of Levy et al. ('143) does not remedy the deficiencies of the combination of references found as applied to the previous claims (i.e., the independent claims). Thus, even IF Levy et al. ('143) teach what the Examiner purports it teaches the combination still fails to teach or suggest treating feeder vessels in the extrafoveal area.

The same can be said for the combination of Levy et al., Jampol et al., Miller et al. and Levy et al. ('143). Accordingly the rejection may properly be withdrawn.

Claims 1-8, 10-17, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy et al., in view of Jampol et al., and further in view of Roach (Eye Net Magazine March 2001). Roach is applied for the alleged teaching of a digital imaging system for high-speed indocyanine green angiography coupled with a scanning laser ophthalmoscope. Even if there is some suggestion to combine Roach with the other references, which there is not, the result fails to satisfy the deficiencies of the independent claims as describe above. Roach does not teach

or suggest all of the elements of Applicants' claimed invention, e.g., treating feeder vessels in the extrafoveal area with doses higher than the typical dose used in the foveal area.

Claims 1-8, 10-17, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy et al., in view of Jampol et al., and further in view of Miller et al., and further in view of Roach (Eye Net Magazine March 2001). Applicants respectfully traverse this rejection.

The combination of Levy et al., Jampol et al. and Miller et al. were addressed above. The combination of Levy et al., Jampol et al. and Roach were addressed above. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Claims 1-8, 10-18, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy et al., in view of Jampol et al., and further in view of LumaCare. Applicants respectfully traverse this rejection.

The combination of Levy et al., Jampol et al. were addressed above. The Office attempts to overcome the deficiencies of the foregoing reference as it relates to non-coherent light of claim 18 by citing LumaCare. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Claims 1-8, 10-18, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy et al., in view of Jampol et al., and further in view of Miller et al., and further in view of LumaCare. Applicants respectfully traverse this rejection.

The combination of Levy et al., Jampol et al. and Miller et al. were addressed above. The combination of Levy et al., Jampol et al. and LumaCare were addressed

above. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Respectfully, the Examiner appears to attempt to fill in any and all gaps with a general statement, "A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the might reasonably infer from the teachings." The Examiner appears to be attempting to infer upon an inference of a combination that might infer the claimed invention; this cannot be done. Applicants respectfully submit that the statement that the Examiner appears to be relying upon is related to "direct anticipation" and inference not obviousness and inference. The rejections pending are not direct anticipation by are rather an inference that might be inferred by a combination of references.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

GAVRILOVICH, DODD & LINDSEY LLP

Date: September 2, 2008

By: Joseph R. Baker, Jr./

Joseph R. Baker, Jr.

Registration No. 40,900

4445 Eastgate Mall, Suite 200
San Diego, California 92121
(760) 479-0474